

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF IOWA
DAVENPORT DIVISION**

THE UNIVERSITY OF IOWA and
THE UNIVERSITY OF IOWA
RESEARCH FOUNDATION,

Plaintiffs

v.

AMGEN, INC., a Delaware
corporation; IMMUNEX
CORPORATION, a Washington
corporation; AMGEN USA INC., a
Delaware corporation; AMGEN
MANUFACTURING, LIMITED, a
Bermuda Corporation; and IMMUNEX
RHODE ISLAND CORPORATION, a
Delaware corporation,

Defendants

Civil Action No. _____

COMPLAINT AND JURY DEMAND

COMPLAINT

Plaintiffs, The University of Iowa (“University”) and The University of Iowa Research Foundation (“UIRF” or, collectively with the University, as “IOWA”), allege as their Complaint the following:

NATURE OF ACTION

1. This is an action for infringement of U.S. Patent Nos. 5,168,062 (the “‘062” patent) and 5,285,839 (the “‘839 patent”). (The ‘062 patent and the ‘839 patent will be referred to collectively herein as the “Iowa Patents.”) The Iowa Patents are based on inventions of Mark Stinski, Ph.D., the University of Iowa’s Carver College of Medicine Distinguished Professor of Microbial Virology, who assigned the patents to UIRF.

2. The Iowa Patents are directed to what is commonly referred to as the “CMV Promoter,” which is a fundamental tool used in the biotech industry to enhance the manufacture of vaccines and therapeutics, many of which are the key compositions found in life-saving pharmaceuticals.

3. The Iowa Patents are important and successful. UIRF has granted 113 active licenses, including 13 royalty-bearing products, to the Iowa Patents allowing research institutions and commercial ventures to use the inventions, with the royalties received serving to help sustain the University and its community. However, the defendant Amgen, Inc. (“Amgen”), one of the largest biotech companies in the world, and its affiliates have for many years infringed the Iowa Patents with full knowledge of them.

4. Amgen infringes the Iowa Patents when, for example, but without limitation, it and its affiliates use the inventions to manufacture drugs such as its multi-billion dollar blockbuster drug Enbrel[®]. Despite diligent efforts by the Plaintiffs to persuade Amgen to respect the Iowa Patents, Amgen has refused to do so. Accordingly Plaintiffs have no choice but to bring this action for patent infringement.

THE PARTIES

5. The University is a state instrumentality of the State of Iowa and a public institution of higher education created by the Iowa legislature and located in Iowa City, Iowa.

6. UIRF is a 501(c)(3) corporation organized and existing under the laws of Iowa with its principal place of business at 2660 University Capitol Centre, Iowa City, Iowa 52242-5500. Although separately incorporated in 1975, the UIRF is an affiliated organization of the University and acts as an instrumentality of the University by performing functions that the University would itself ordinarily carry out. Specifically, the University has designated the UIRF as the owner of its patent rights and manager of its interests in qualifying inventions. Pursuant to this designation, the UIRF is organized and operates to support the research and

educational missions of the University by transferring University-invented technologies to the marketplace for the benefit of the University, its inventors, the State of Iowa, and society at large. Through the commercialization of University intellectual property and the formation of new business ventures to support those technologies, the UIRF also serves a key role in the University's efforts to support and enhance economic development in the State of Iowa.

7. Upon information and belief, Amgen is a corporation organized and existing under the laws of Delaware. Amgen maintains an office at One Amgen Center Drive, Thousand Oaks, California 91320-1799. Upon information and belief, Amgen is registered to do business in Iowa and has a registered agent or reserving party at 2222 Grand Avenue, Des Moines, Iowa 50312.

8. Upon information and belief, Immunex Corporation ("Immunex"), a wholly-owned subsidiary of Amgen, is organized and existing under the laws of the State of Washington with its principal place of business in Thousand Oaks, California. Upon information and belief, Immunex is registered to do business in Iowa and has a registered agent or reserving party at 2222 Grand Avenue, Des Moines, Iowa 50312.

9. Upon information and belief, Amgen USA Inc. ("Amgen USA"), an Amgen affiliate, is organized and existing under the laws of the State of Delaware

with its principal place of business in Thousand Oaks, California. Upon information and belief, Amgen USA is registered to do business in Iowa and has a registered agent or reserving party at 2222 Grand Avenue, Des Moines, Iowa 50312.

10. Upon information and belief, Amgen Manufacturing, Limited (“Amgen Mfg.”), an Amgen affiliate, is a company organized and existing under the laws of Bermuda with its principal place of business in Juncos, Puerto Rico.

11. Upon information and belief, Immunex Rhode Island Corporation (“Immunex R.I.”), an Amgen affiliate, is organized and existing under the laws of the State of Delaware with its principal place of business in West Greenwich, Rhode Island.

JURISDICTION AND VENUE

12. This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. § 1338(a) because this is a case arising under the patent laws of the United States (35 U.S.C. § 1, *et seq.*, and particularly 35 U.S.C. § 271), as well as pursuant to 28 U.S.C. § 1331 because this matter involves a federal question.

13. Venue is proper in the Southern District of Iowa under 28 U.S.C. §§ 1391 and 1400(b).

14. This Court has personal jurisdiction over Defendants and this is the proper venue for this action because Defendants, individually and by virtue of joint and several cooperative activity, have solicited and transacted business within, negotiated with UIRF regarding the Iowa Patents, caused foreseeable injury within, and otherwise engaged in conduct both within and without the State of Iowa and the Southern District of Iowa sufficient to confer upon this Court the right and authority to exercise personal jurisdiction over these defendants consistent with principles of due process and to render this District the proper venue for this action.

THE PATENTS-IN-SUIT

15. On December 1, 1992, the United States Patent and Trademark Office duly and legally issued the '062 Patent, entitled "Transfer Vectors and Microorganisms Containing Human Cytomegalovirus Immediate-Early Promoter-Regulatory DNA Sequence" and naming Mark F. Stinski as inventor. UIRF is the owner of all right, title, and interest in and to the '062 Patent.

16. On January 31, 1995 the United States Patent and Trademark Office duly and legally issued the '839 Patent, entitled "Transfer Vectors and Microorganisms Containing Human Cytomegalovirus Immediate-Early

Promoter-Regulatory DNA Sequence” and naming Mark F. Stinski as inventor.

UIRF is the owner of all right, title, and interest in and to the ‘839 Patent.

FACTUAL ALLEGATIONS

17. The Iowa Patents represent important advances in biotechnology science and industry.

18. The Iowa Patents include biotechnology tools used to promote the expression of genes and production of proteins that are important in the production of many life saving protein-based drugs now on the market.

19. The pharmaceutical and biotechnology community, both commercial and academic, has wholeheartedly adopted and widely licensed the Iowa Patents.

20. The Iowa Patents have been a tremendous commercial success. UIRF has granted 113 active licenses, including 13 royalty-bearing products to the ‘062 and ‘839 Patents.

21. To date, Plaintiffs have received millions of dollars in licensing revenue resulting from licenses to the Iowa Patents.

22. Defendants, individually and jointly and severally, infringe the Iowa Patents directly and indirectly, when they, for example and without limitation to the proof of other infringing acts, illegally use the Iowa Patents to manufacture

pharmaceutical products including, without limitation, at least Enbrel[®] and Vectibix[™], that are sold in the United States and throughout the world.

23. Enbrel[®] (generic name: etanercept) is a human therapeutic product imported, manufactured, sold, and offered for sale by Defendants individually and jointly and severally.

24. Defendants, individually and jointly and severally, illegally use or contribute to the use or induce the use of compositions covered by one or more claims of the Iowa Patents to manufacture the pharmaceutical product Enbrel[®].

25. Vectibix[™] (generic name: panitumumab) is a human therapeutic product imported, manufactured, sold, and offered for sale by Defendants individually and jointly and severally.

26. Defendants, individually and jointly and severally, illegally use or contribute to the use or induce the use of compositions covered by one or more claims of the Iowa Patents to manufacture the pharmaceutical product Vectibix[™].

COUNT I

INFRINGEMENT OF U.S. PATENT NO 5,168,062

27. Plaintiffs repeat, reallege, and incorporate the foregoing allegations of paragraphs 1-26, as if set forth fully herein.

28. Defendants, individually and jointly and severally, have infringed, directly or indirectly, one or more claims of the '062 patent in violation of 35 U.S.C. §§ 271.

29. Upon information and belief, Defendants have knowledge of the '062 patent, and have not ceased their infringing activities. Defendants have willfully and deliberately, in disregard of Plaintiffs' lawful rights, infringed the '062 patent, rendering this case "exceptional" as that term is set forth in 35 U.S.C. § 285 and warranting an award of treble damages under 35 U.S.C. § 284.

COUNT II

INFRINGEMENT OF U.S. PATENT NO. 5,285,839

30. Plaintiffs repeat, reallege, and incorporate the allegations of paragraphs 1-29, as if set forth fully herein.

31. Defendants, individually and jointly and severally, have infringed, directly or indirectly, one or more claims of the '839 patent in violation of 35 U.S.C. §§ 271.

32. Upon information and belief, Defendants have knowledge of the '839 patent, and have not ceased their infringing activities. Defendants have willfully and deliberately, in disregard of Plaintiffs' lawful rights, infringed the '839 patent, rendering this case "exceptional" as that term is set forth in 35 U.S.C. § 285 and warranting an award of treble damages under 35 U.S.C. § 284.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment:

- (a) That the Defendants, individually and jointly and severally, directly and indirectly infringe one or more claims of U.S. Patent No. 5,168,062;
- (b) That the Defendants, individually and jointly and severally, directly and indirectly infringe one or more claims of U.S. Patent No. 5,285,839;
- (c) That the Plaintiffs are entitled to monetary damages in an amount to be determined by the jury;

- (d) That the Defendants' illegal activities were willful, justifying enhanced damages;
- (e) That this case is exceptional, justifying an award to the Plaintiffs of attorneys' fees and costs incurred in this action, pursuant to 35 U.S.C. § 285;
- (f) Awarding Plaintiffs prejudgment interest and costs pursuant to 35 U.S.C. § 284; and
- (g) Granting Plaintiffs such other and further relief as the Court deems proper.

PLAINTIFFS DEMAND TRIAL BY JURY ON ALL ISSUES TRIABLE BY A JURY IN THIS CASE.

Respectfully submitted, this day 8th day of September, 2008.

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